r. High occupational exposure, exceeding the allowable limits
s. Proper use of personnel monitors

Who are the **operators of fluoroscopes** in the states? Generally, the answer was licensed practitioners and in some cases, licensed radiologic technologists who would be under the supervision of a licensed practitioner. Techs were also using a fluoroscope while assisting a fluoroscopist, while using a therapy simulator, in performing localizations, and for obtaining static images. There were also indications that techs were using a fluoroscope to aid them in positioning, then taking a radiograph (this was especially the case for an overhead fluoro system with remote operation).

It appears that California and only a few other states **specifically license a person to perform fluoroscopy.** For most states, it is within the scope of practice.

Most states, of course, have a **maximum allowable entrance exposure rate** compatible with the federal standard. About one-third of the states also have some sort of standard or recommendation for a **"typical" patient exposure rate.** For automatic exposure rate control systems, however, this is difficult to measure without a standard phantom (Missouri uses 0.1 inch copper, and California uses 7 and 7/8 inch Lucite). Hopefully, the FDA phantom will fulfill this need.

As to **how many high level control-capable fluoro systems** each state identified, that answer varied, of course, depending on the size of the state. The majority of states answered between 1 and 30, but the most interesting answer overall was that this number was unknown, and/or only a guess.

Reported incidents involving fluoroscopy ranged from zero to 28, but this answer did NOT depend on size of the state, as one would expect. Conclusion: reporting of patient or occupational over-exposures from fluroscopy (or any x-ray machine-related incident) is inconsistent and weak. The other, and most outstanding, conclusion from this whole survey was that 99% of the reported occupational overexposure incidents were of cardiologists.

SSR4 COMMITTEE'S
HIGH LEVEL FLUOROSCOPY
SURVEY FORM

On October 16 and 17, 1992, the ACR and the FDA are sponsoring a high level fluoroscopy workshop in the Washington, DC area, called: "Strategies for Improvements in Performance, Radiation Safety and Control." The goal of the workshop is to permit a discussion of improvements in performance, radiation safety and control of fluoroscopy among clinical users, medical physicists, researchers, manufacturers and representatives of government agencies. Recommendations coming out of the workshop can provide a basis for action by professional organizations, users, and regulatory agencies, both state and federal.
One of the presentations at this workshop is a view of fluoroscopy from the states' perspective. I need your help in providing this input to the workshop. Please take a few minutes and answer these questions, then choose one of these multi-media methods to relay the information to me (I would appreciate your doing so by September 30):

telephone, voice - 206 464 5408
telephone, fax - 206 464 7081
Prodigy message - XDHP04A
mail - Dept of Health, Rm 701
1511 3rd Ave
Seattle WA 98101-1632

1. **Who can operate** a fluoroscope in your state? Licensed practitioner only?_____; Radiologist only?_____; Technologists?_____. Explain, if necessary.

2. Does your state specifically **credential, authorize, or license** ANYONE who operates a fluoroscope, be they physicians or technologists? Explain.

3. Most states have **maximum** allowable EERs (entrance exposure rate), i.e., 10 R/min. Does your state have a **EER standard for a "typical"** patient size? _____Y_____N (California, for example, will answer "yes" to this, I believe)

4. Roughly how many **High Level control**-capable fluoroscopic systems do you think you have in your state? Zero_____; 1 to 10_____;
11 to 20_____; 21 to 30_____; more than 30_____.

5. **How many** reported incidents, over-exposures, etc have you had since January 1, 1992, involving fluoroscopy of any kind. Describe.

6. What are your **major concerns** about fluoroscopy? Please elaborate.

a. Mobile C-Arms_____.
b. Stationary C-arms_____.
c. Remote/special procedure systems_____.
d. High Level Control_____.
d. Rate limits_____.
e. Training and user authorization_____.
e. Occupational Exposures_____.
f. Other????_____Please explain.

Thank you for your help!!! -Mike Odlaug

STATE AUTHORITY AND REGULATIONS BASED ON:

- CRCPD
- FDA
- NCRP
- ADVISORY COMMITTEES
- LOCAL PROFESSIONAL ASSOCIATIONS

STATE LAWS, REGULATIONS, AND PROCEDURES DIFFER:

- Fees and Fines
- Inspection Frequency
- Inspector Type
- Inspection Content
- Report and Citation Format

STATE PROGRAMS

1. **Cover all X-ray Facilities**

   (veterinarians, industry, etc.)

2. **Certified or Uncertified Machines**

STATE REGULATIONS ADDRESS USE OF X-RAY SYSTEMS

(FDA COVERS MACHINE PERFORMANCE)

1. **Who can operate them**

2. **Who needs to be licensed**

3. **Conditions of use**

STATES ENFORCE RULES TO REDUCE:

1. OCCUPATIONAL EXPOSURE

2. PATIENT EXPOSURE

3. PUBLIC EXPOSURE

STATES ALSO REGULATE:

1. PERSONNEL MONITORING

2. OPERATOR TRAINING/CREDENTIALING

3. FILM PROCESSING

4. ROOM SHIELDING

SSRCR

SUGGESTED STATE REGULATIONS

FOR THE

CONTROL OF RADIATION

FLUOROSCOPY, PART F.5

PART F.5 OF THE SSR ADDRESSES:

- LIMITATION OF THE USEFUL BEAM
- ACTIVATION OF THE FLUORO TUBE
- EXPOSURE RATE LIMITS
- BARRIER TRANSMISSION
- INDICATION OF TECHNIQUE FACTORS
- SSD
- TIMER
- CONTROL OF SCATTER
- THERAPY SIMULATORS

Review of Fluoroscopy Equipment Operation and Performance

Pei-Jan Paul Lin, Ph.D.

Review Of Fluoroscopy Equipment Operation & Performance

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Chairman, Diagnostic X-ray Imaging Committee
American Association of Physicists in Medicine

I. Fluoroscopic Equipment Classification

In this presentation, various fluoroscopic imaging equipment are classified in terms of their mechanical [geometrical] arrangement. A brief description of these systems; Conventional (Undertable) Fluoroscopy, Remote Control (Overtable) Fluorosocpy, Mobile C-arm, (Special Procedure) Stationary Type C-arm, and Special Purpose Fluoroscopy [Urology-Cystoscopy, Lithotripter] will be discussed.

If one focuses on the image recording media in a typical fluoroscopy equipment, there are, basically, two different image recording [receptors] available. The first image receptor [recoding media] is the FULL SIZE CASSETTE spot filming device. The spot filiming device is essentially a radiographic mode operation of the fluoroscopy equipment. We are more interested in the second image receptor; the image intensifier and the subsequent imaging chain. Furthermore, the image intensifier provides two totally different imaging recording channels; (1) the optical channel using photographic [photofluorosgraphic] cameras, and (2) the electronic channel employing the television cameras.

II. Various Modes Of Fluoroscopic Equipment Operations and The Image Intensifier Input Exposure Level [IIIEL]

The fluoroscopic imaging equipment produce a wide range of patient exposures depending on the particular image recording media is (are) employed. The fluoroscopic radiation output may be generated under (a) the normal condition; Normal Fluoroscopy, (b) boosted condition; High Level Output Fluoroscopy, or (c) the modulated condition; Reduced Duty Cycle Fluoroscopy, and Pulsed Fluoroscopy. The modulated condition fluoroscopy is often coupled with image insert/retention devices such as video disk, last image hold, etc. in an attempt to reduce the patient exposure. While most of us do not consider the pulsed cine exposure as one of these patient exposure reduction schemes, the cine photofluorographic camera operation is actually one of the most significant examples of patient exposure reduction as the pulsation of the x-rays is synchronized to that of the cine camera shutter operation. [Of course, the total pateint exposure of a cine cardiac studies is among the highest of various diagnostic x-ray examinations.]

The patient exposure under fluoroscopic imaging varies substantially due to the wide variation of recording device sensitivity, and the efficiency of the image intensifier itself. There are several physical factors affecting the overall imaging system sensitivity. Among them, the most pronounced is the [active] physical size of the image intensifier input phosphor for a given image intensifier. In order to maintain the same signal-to-noise ratio of an image observed at the output phosphor, when the active phosphor size is reduced from 9" to 6", the input phosphor must receive twice more radiation than before. That is the image intensifier input exposure level [IIIEL] must be increased by a

factor of TWO.

To raise the IIIEL by a factor of two, one does not necessarily have to increase the patient exposure by a factor of two. The IIIEL can be raised by increasing the x-ray tube potential, thus increasing the ability of the x-rays to penetrate {approximately proportional to from the third to fifth power of the x-ray tube potential [Penetration α kVp^3, or α kVp^5]}, while the radiation exposure increases proportional to the square of the tube potential {approximately; Exposure α kVp^2}. The IIIEL has been assigned two different units depending on the imaging mode or the recording media, e.g., "μR/sec" for fluoroscopy and "μR/frame" for photospopt camera, cine camera, etc.

"Calibration of Fluoroscopy Equipment" in the physics and/or the engineering community actually refers to setting up the IIIEL to the correct operational level for proper image recording; that is "noise" limited. The same term, however, is employed by various State Agencies to setup, or limit fluoroscopic radiation output to the maximum patient entrance exposure rate of 10 R/min under normal fluoroscopic operation.

The advent of improved and advanced design image intensifiers in the recent years has established a "de facto" standard of the IIIEL. Listed in Table I. is the typical calibration of IIIEL one can expect to find on most fluoroscopic imaging systems.

Table I. Typical IIIEL Values For 9" Image Intensifier Input Phosphor Size

Imaging Mode	IIIEL
Fluoroscopy	75-100 "μR/sec"
100 mm Photospot Camera	100 "μR/frame"
35 mm Cine Camera	10-15 "μR/frame"
Digital Fluoroscopy	75-100 "μR/sec"
Digital Spot Imaging	75-100 "μR/frame"
Digital Cine Angiography	10-15 "μR/frame"
Digital Subtraction Angio	500-1000 "μR/frame"

The calibration of IIIEL in reality sets up the reference point for the automatic exposure control circuits such that the radiation impinging on the image intensifier is determined to be at its steady state. The automatic exposure control [AEC] circuits have been given various technical terms depending on the particular imaging mode one is interested. For examples; (a) the AEC for the fluorosocopy system is referred to as the Automatic Brightness Control [ABC] circuit or the Automatic Brightness Stabilization [ABS] circuit, and (b) the automatic [optimum] tube potential seek circuit in various cine mode operations. Equipment vendors have designed various sophisticated automatic control circuits to optimize the equipment operation so that the medical team's attention is on the patient care rather than "how" to run or operate the equipment in setting up the radiographic technical factors for proper exposure of the imaging chain.

III. Fluoroscopic Automatic Brightness Control Circuit

The focus of this ACR/CDRH meeting is on the high exposure level of the fluoroscopic equipment, and the attention of this presentation is on the ABC or the ABS circuit of the fluoroscopy systems . There are basically two types of ABC circuit designs employed in the fluoroscopic equipment currently on the commercial market. They are either the kVp-preferred ABC, or the mA-preferred ABC. Some discussionson of these two control circuits are given in the following;

III-A. The kVp-preferred ABC Circuit

In this type of ABC, the x-ray tube potential is the leading physical parameter that varies in accordance to the patient thickness. The x-ray tube current is either, (a) preset to a constant value which may be adjusted by the fluoroscopist, or (b) a function of the tube potential which is a predefined {and often selectable by the installation engineer, or by the user} in the ABC logic design. The relationship between the tube potentail and the tube current can be graphically expressed and one such a typical example is depicted in Figure 1.

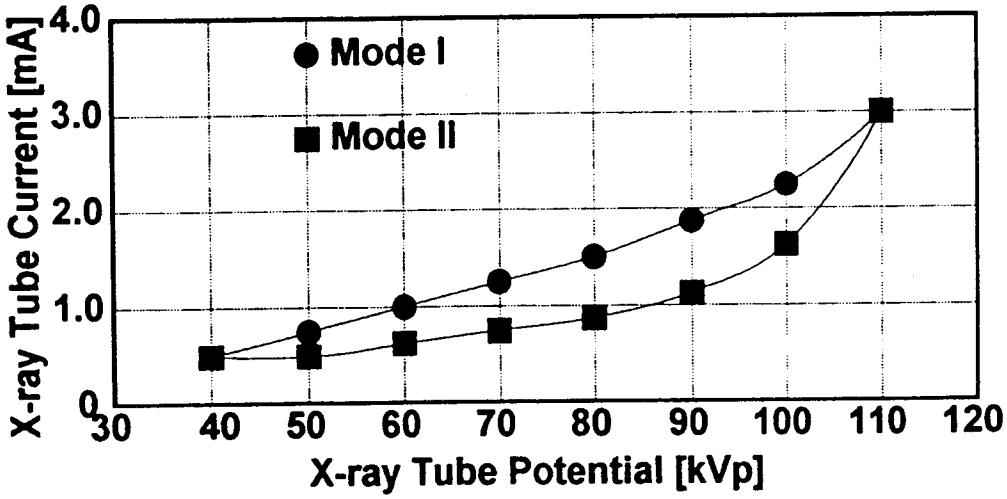

Figure 1. X-ray Tube Current VS. X-ray Tube Potential

The fluoroscopic technique factors starts at [0.5 mA, 40 kVp] and ends at [3.0 mA, 110 kVp]. The ending point may be changed to meet with the maximum output limitation of 10 R/min, by rasing the shifting the maximum "mA" value allowable. Under the "Boosted" mode the upper limit is raised to an "mA" value that exceeds the 10 R/min limitation while the audible "ALARM" is activated. Notice that there are two different response curves [relationship] available.

III-B. The mA-preferred ABC Circuit

The mA-preferred ABC circuit requires that the fluoroscopist select an appropriate tube potential; 60 kVp for a young child, or 85 kVp for an average size adult patient. The tube current is then automatically varied to achieve the steady state. The tube potential is

varied as the secondary parameter if, for instance, the required mA-value at the selected tube potential will exceed the 10 R/min limitation. This type of ABC circuit design requires a lengthy calibration procedure to ensure that the 10 R/min limitation is not violated at any of the available tube potential settings for the fluorsocopy operation.

IV. The Patient Exposure

Due to the time and space limitation, the patient exposure of the kVp-preferred ABC circuit is employed to illustrate the variation of both x-ray tube potential [kVp], and the tube current [mA] as a function of the patient thickness; using the Plexiglas phantom as the patient. In addition, the variation of the IIIEL and the patient exposure as a function of the patient thickness is shown. The experimental arrangement of this measurement is depicted in Figure 2.

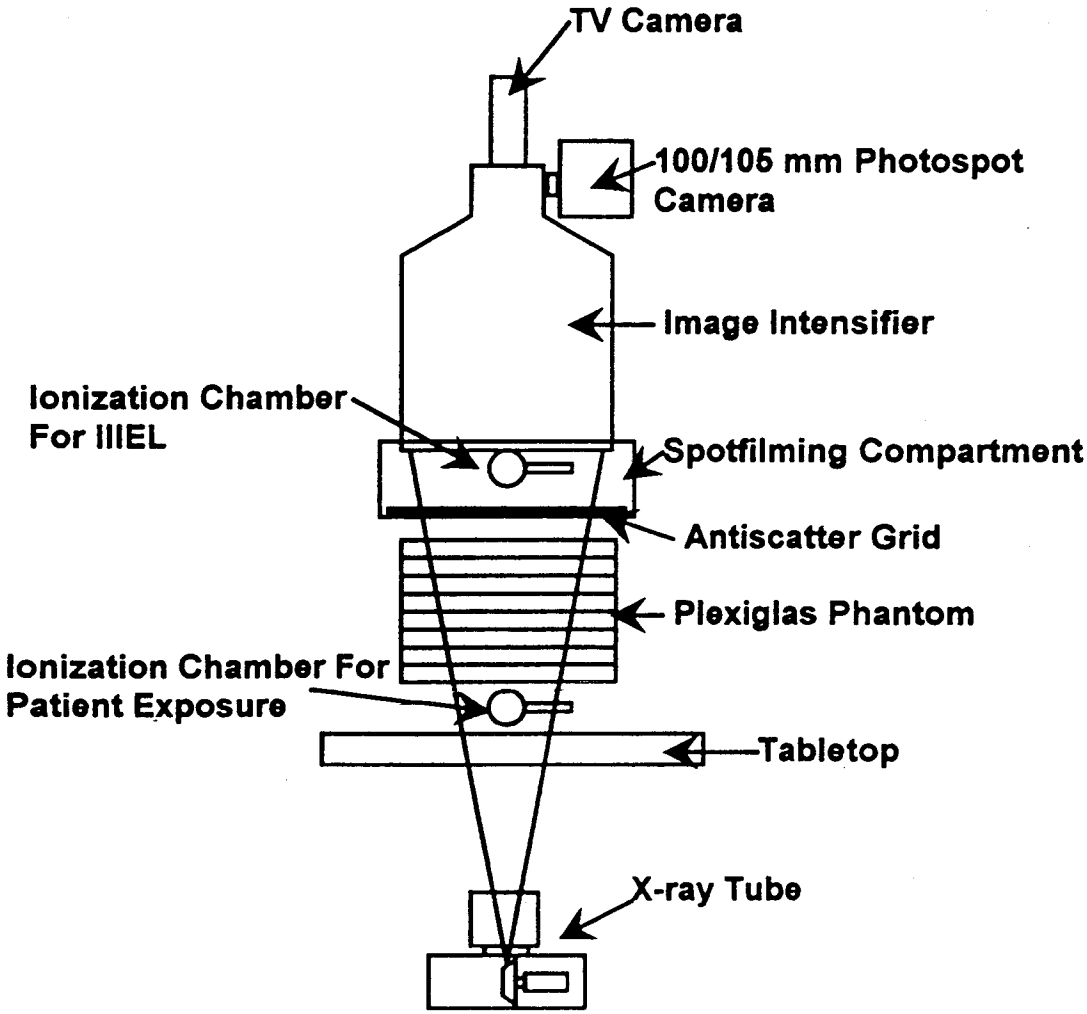

Figure 2. Geometrical Arrangement of Measurements For The Image Intensifier Input Exposure Level and Patient [Entrance] Exposure.

The data [based on a 6" CsI image intensifier] obtained are plotted and depicted in Figures 3, and 4. The typical situation is signified with the dotted lines in these two figures at the phantom thickness of 8", i.e., (a) the tube potential: 93 kVp, the tube current 1.8 mA from Figure 3, and (b) the IIIEL 28 $\mu R/sec$, the patient exposure 4 R/min from Figure 4.

For the consistensy with Table I, the patient exposure under a 9" image intensifier is givem in Table II. It should be noted that the values given in Table II are based on a very small number of data samples and should not be taken to understand as statistically valid data.

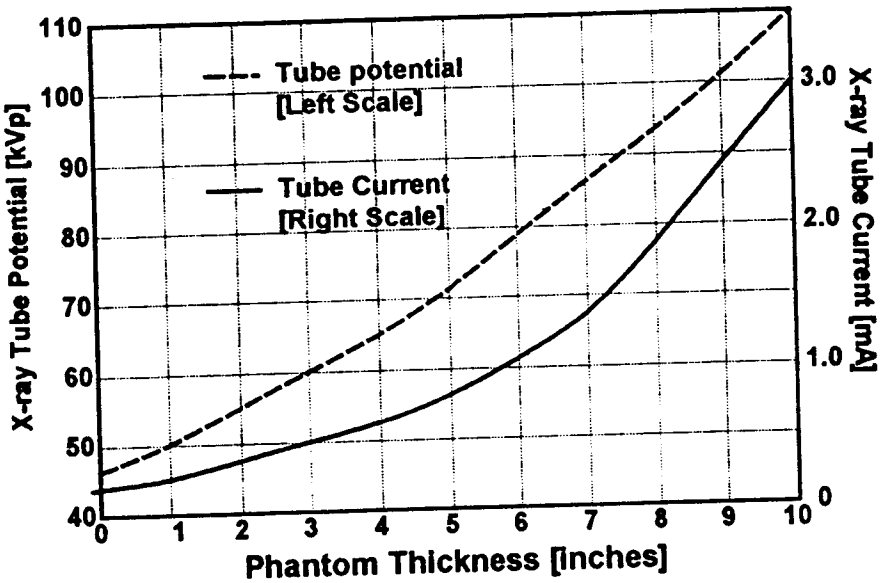

Figure 3. "kVp" & "mA" VS. Phantom Thickness

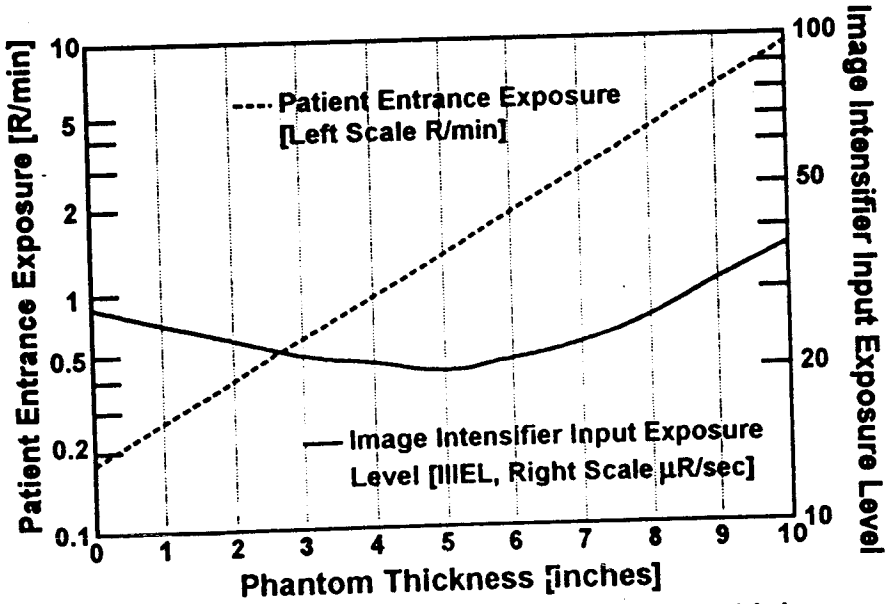

Figure 4. Patient Exposure, & IIIEL VS. Phantom Thickness

Table II. Typical Patient Exposure Under 9" Image Intensifier Input Phosphor Size For An Averaged Size Patient [8"-10" Plexiglas Phantom]

Imaging Mode	Patient Exposure
Fluoroscopy	2-3 "R/min"
100 mm Photospot Camera	75-100 "mR/frame"
35 mm Cine Camera	10-15 "mR/frame"
Digital Fluoroscopy	< 2-3 " R/min"
Digital Spot Imaging	50-100 "mR/frame"
Digital Cine Angiography	10-15 "mR/frame"
Digital Subtraction Angio	350-500 "mR/frame"

V. Radiation Safety Problems In Fluoroscopic Operations

There are three basic radiation safety problems in the operation of fluoroscopic imaging equipment. The first problem has to do with the so called (a) high contrast fluoroscopy, (b) turbo mode fluoroscopy, or (c) high definition fluoroscopy to name a few. These names are given to the High Level Output fluoroscopy, and the only requirements are that a positive action of intent by the operator to activate the high level output fluoroscopy [HLOF], and there must be an audible warning, when the fluoroscopic equipment is being operated under this mode. The second problem is that the 10 R/min fluoroscopic output limitation is no longer required so long as an "image recording" is performed concurrently with the fluoroscopic study. Both problems are caused by the fact that there is no upper limit of fluoroscopic radiation output. The third problem exists mainly in the cardiovascular angiography equipment where implementation of the 10 R/min limitation is not necessarily easily adopted due to the equipment design.

V-1. The Problems Of Boosted Mode [High Level Output] Fluoroscopy

As mentioned previously, currently there is no upper limit set forth by the regulatory agencies when a fluoroscopy equipment is operated under the high level output mode. Fluoroscopic radiation output as high as 40 R/min have been detected in the filed. There is certainly no need for such a high radiation output to image any examinations conducted in the hospitals. It is particularly trublesome to find this kind of ultra high level of radiation output is permitted on mobile C-arm fluoroscopy equipment.

In hospitals where this investigator is retained as a radiological physics consultant, all HLOF systems are limited to less than 20 R/min. Mobile C-arm fluoroscopy, in particular are limited to less than 15 R/min depending on the application of the mobile fluoroscopy system. In most cases, the high level fluosocopy mode of operation is disabled, physically and electronically. In cardiovascular angiography suites, the HLOF mode is available and preset to less than 15 R/min [neuro and visceral

angiography] and 20 R/min [cardiac catheterization laboratory, electro-physiology laboratory].

The HLOF is available in case such a boosted output is necessary to visualize the anatomy in question. However, according to the anguiographers and cardiologists in these hospitals, the HLOF is very seldom employed.

V-2. The Problems Of Boosted Mode [High Level Output] Fluoroscopy With Recording

Essentially, the abuse and taking advantage of the loop hole by some of the equipment service organizations and often demanded by the end users of less than adequately maintained fluoroscopy equipment to boost the fluoroscopic radiation output beyond 10 R/min by simply connecting a video tape or video cassette recorder [VTR, and VCR] is of major concern from radiation safety point of view.

Unless the recorded images are employed for diagnosis, the increased fluoroscopic output cannot be justified. The language of the law partaining to this problem requires substantial rewriting so that the obvious abusive situation can be eliminated.

V-3. The 10 R/min Limit Of Fluoroscopy Output Under Cardiovascular Imaging

The maximum fluoroscopic output is measured on the tabletop for the conventional fluoroscopy systems, and 30 cm above the tabletop for the remote control type fluoroscopy [including the urology/cystoscopy type fluoroscopy] systems. For a mobile C-arm, and any other C-arm/U-arm type equipment, the maximum flurosocopic output is measured at 30 cm from the image intensifier.

The maximum fluoroscopic output, or more appropriately referred to as the fluoroscopic [patient] entrance exposure is measured 30 cm in front of the image intensifier for the fluoroscopic equipment with a C-arm/U-arm configuration. The frontal plane geometry, this measurement protocol can be considered satisfactory. Hoever, for the lateral plane geometry, the location of radiation measurement, namely 30 cm from the I.I., does not realiy represent the patient entrance exposure. Although, less than satisfactory, this measurement protocol is employed to setup the maximum radiation output of the fluoroscopy.

The problem arises from the additional fluoroscopic output control circuit that are implemented by at one manufacturer at this point in time to compensate for the sourct-to-image receptor distance [SID]. For the discussion purpose, let us call this fluoroscopic output control circuit, an SID compensated fluoroscopy control [SIDCFC]. In addition to the ABC, the SIDCFC is also designed to maintain the IIIEL to a constant as the SID is varied.

Consider a C-arm fluoroscopic system, referring to Figure 5, with variable SID of 90 cm to 140 cm with standard clinical operation performed at 100 cm SID. By law, the maximum fluoroscopic output is measured at 30 cm in front of I.I., namely 70 cm from the focal spot. The tabletop is located approximately 30 cm from the I.I. (locations "B", and "C"), so that the maximum fluoroscopic output does represent the patient entrance exposure under a typical clinical operation of the system. The patient on the tabletop is thus approximately 70 cm from the focal spot.

Under an extreme condition, if the image intensifier is raised to the maximum SID of 140 cm, the SIDCFC is activated so that the maximum fluoroscopic output at a

location 30 cm from the I.I., namely 110 cm from the focal spot is incresed to 10 R/min. However, the patient is still located at 70 cm from the focal spot (location "A"). A simple inverse square of distance calculation reveals that the patient could now receive up to 2.5X radiation, i.e., $[110/70]^2 = 2.469$, approximately 25 R/min. This particular equipment manufacturer has designed the fluorosocpy system such that the SIDCFC mode is disabled when the boosted mode [high level output] is activated.

The SIDCFC is actually useful where the height of the angiographer comes into play, as the examination tabletop height is adjusted for the height most convenient for the angiographer or the cardiolohgist performing catherization procedures. The entire frontal plane mechanism may be raised or lowered to obtaine the ideal isocentric geometry. It is also a normal practice to lower the I.I. as close as possible and practical to the patient, so such an extreme situation described does not occur often. However, the potential of producing a very high fluoroscopic radiation is intrinsic with the system design and attention to this fact is warranted.

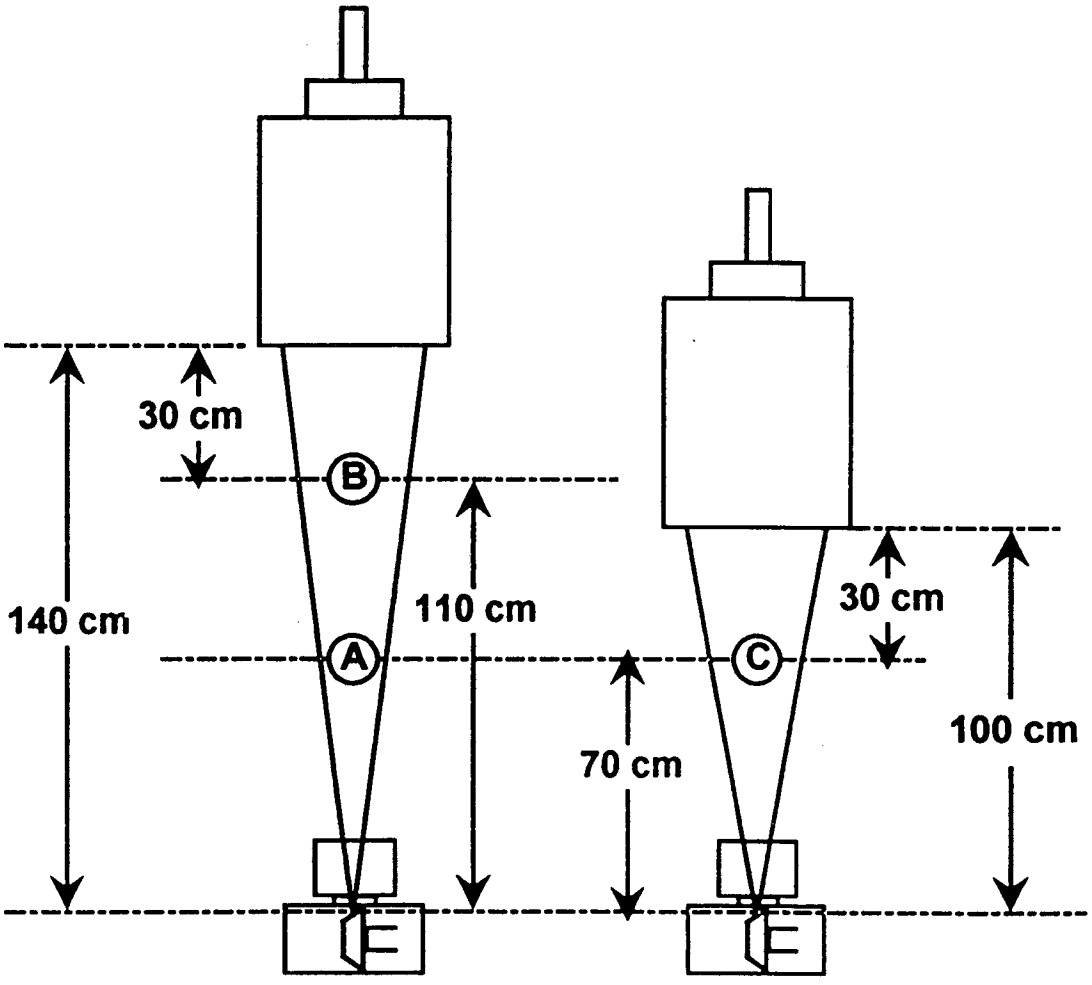

Figure 5. Illustration of Increased Patient Entrance Exposure Rate. When the SID is increased from 100 cm to 140 cm, the radiation output is compensated automatically to account for the increased SID.

Review Of Fluoroscopy Equipment
Operation & Performance

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Chairman
Diagnostic X-ray Imaging Committee
American Association of Physicists in Medicine

Various Recording And Image Processing
Media Employed For Video Signals

Analog Video Tape Recorder [AVTR]
Analog Video Cassette Recorder [AVCR]
Analog Video Disk [AVD]
Digital Tape Recorder [DVTR]
Digital Video Cassette Recorder [DVCR]
Digital Video Disk [DVD]

[Digital] Solid State Memory

Classification By Mechanical Arrangement

[1] Conventional Fluoroscopy [Undertable]
[2] Remote Control Fluoroscopy [Overtable]
[3] C-arm/U-arm Type Fluoroscopy
  (3a) C-arm Mobile Fluoroscopy
  (3b) Special Angiography Suite
[4] Special Purpose Fluoroscopy
  (4a) Urology/Cystoscopy Fluoroscopy
  (4b) Lithotripter Fluoroscopy

The image quality and the patient exposure are both dependent, to a large extent, on the amount [flux] of x-rays impinging on the input phosphor of the image intensifier, e.g., the Image Intensifier Input Exposure Level, or the IIIEL is the fundamental physical parameter that determines the Signal-to-Noise [S/N] ratio of the image.

Image Receptors of Fluoroscopy

[1] Direct X-ray [Radiographic] Exposure:
  Full Size Cassette/Intensifying Screen.
  Film Changers.
[2] Image Intensifier:
  (2a) Photofluorographic Camera
    100/105 mm Photospot Camera
    35 mm Cine Cameras
  (2b) Television Camera
    Normal Fluoroscopy Mode
    High Level Output [Boosted]
    Modulated Mode

Patient Exposure is approximately

proportional to $[kVp]^2$.

while, x-ray penetration power is

proportional to $[kVp]^{3-5}$.

Various Modes Of Operation
Under The TV Camera Imaging

Normal Fluoroscopy
Reduced Duty Cycle Fluoroscopy
Pulsed Fluoroscopy
High Level Output Fluoroscopy
Digital Fluoroscopy [DF]
Digital Spot Imaging {Filming} [DSI]
Digital Subtraction Angiography [DSA]
Digital Cine Angiography [DCA]

Calibration Of Fluoroscopic Imaging Chain:

*Regulatory Use of Calibration:

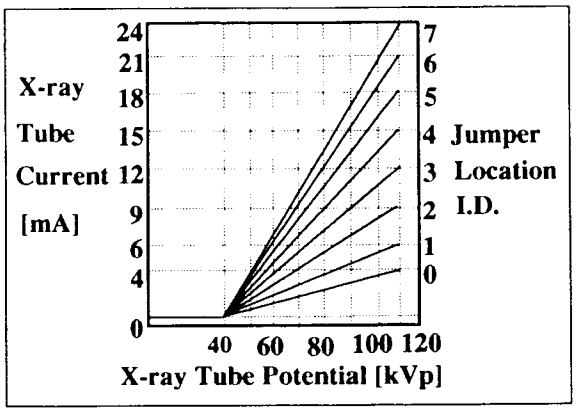
Setting up the upper limit of Fluoroscopic Output, i.e., the 10 R/min Limitation.

*Physics/Engineering Use of Calibration:

To adjust imaging chain to the preset value of image intensifier input exposure level.

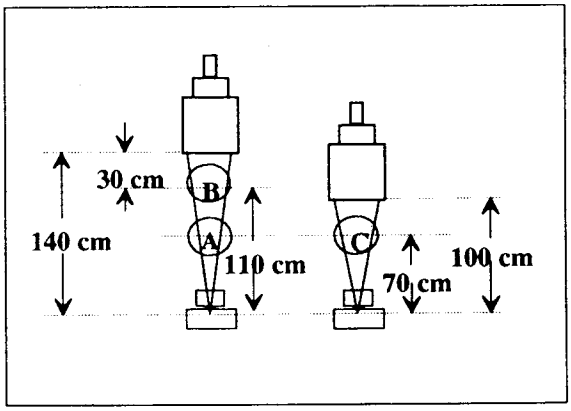
Automatic Brightness Control Circuit For Fluoroscopic Imaging Chain:

* Manual
*kVp-preferred ABC with fixed mA
*kVp-preferred ABC with automatic mA
*mA-preferred ABC with fixed kVp
*mA-preferred ABC with automatic kVp



Some Specific Radiation Safety Problems Of Fluoroscopic Systems

*High Level Output Fluoroscopy
*High Output Permitted with Recording
*Definition of Measurement Protocol



High Level Output Fluoroscopy is needed;

*when LOW CONTRAST objects are the imaging targets. ---- Lithotriptor.
* at extreme viewing angles the body parts become extremely thick. ----- CCL.
*fine catheter is used, high S/N ratio is needed. ------ EP Lab.

At locations "C" and "B" the Patient Entrance Exposure is calibrated to 10 R/min, as both are 30 cm from the input surface of the image intensifier. When the SID is increased from 100 cm to 140 cm, the tabletop remains at the same height. The location "A" is irradiated with a radiation exposure rate of 24.6 R/min.

What We Need Are:

*An UPPER LIMIT of the High Level Output Fluoroscopy System.
*Recorded images must be employed for diagnosis only.
*Understanding the equipment design and operation of various automatic control circuits.

Engineering Considerations for Fluoroscopic Systems

Melvin P. Siedband, P.E.

ENGINEERING CONSIDERATIONS FOR FLUOROSCOPIC SYSTEMS

Melvin P. Siedband
University of Wisconsin

ABSTRACT

There are a number of practical limits imposed on the performance of fluoroscopic systems. Field size, geometry, display hardware, recording devices are some of these. Less obvious are the limits imposed by signal to noise ratio, resolution, contrast, dose and how the system is actually used. This short presentation attempts to define some of these terms and show their importance to the user of fluoroscopic systems.

A BRIEF PRIMER ON NOISE

When anything is made up of independent particles which have an average value, there is an associated randomeness which is not avoidable. Raindrops falling on the sidewalk, photographic grain, and x-ray photons show this same statistical effect. If there is an average of 100 raindrops/cement square and we count the number of actual raindrops on each of several dozen squares, we'll find numbers like: 105, 92, 83, 107, 93, 118, 103, 100, etc. The "DC" part will be 100 and the "AC" part will be around 10. There is an inherent randomness here even though there is an average value. If we try to take a photograph with too little light by using the fastest film and then use chromium intensification to bring out the picture, the image will be too grainy to recognize low contrast objects.

Many years ago, John Coltman conducted experiments to find out just how many light or x-ray photons were needed to see objects of various resolution and contrast. His experiments and the knowledge that a beam of x-rays contains a certain number of photons/square cm/R, means that a certain minimum amount of radiation/image is needed and that this amount of radiation is determined by the resolution of the image, the transmission of radiation by the object, the ability of the detector to use the radiation, the contrast of objects of interest and a few other factors. But the essential fact is that insufficient radiation results in a noisy image which may not be of diagnostic quality and too much radiation is not fair to the patient (or to the practitioner who will receive more scattered radiation). Good practice and common sense require that all radiographic and fluoroscopic images have some noise to indicate that an effort has been made to reduce exposure, but not so much noise that critical information is lost.

Some arithmetic is needed to define the noise or graininess of an image. In any picture element we can assume that there is a certain expected number of grains or image flashes. It can be shown that the randomness or normal variation (standard deviation) is the same as the square root of that number. We define that standard deviation as the noise of that element. If there is an expected

value of 100 grains, the noise is equivalent to 10 grains. If there is an object in front of that element which is expected to absorb 10% of the incident photons, then we can say that a contrast of 10% (approximately) should result and that there would be a signal to noise ratio of 1:1. Your eye cannot see small objects when the S/N is much less than 4:1, more about larger objects later. To raise the S:N, the number of photons/element must be increased. In this example, if the dose is increased by ten times, the S:N will increase by the square root of ten, or 3.16, almost enough to just see an object of 10% contrast. Or we could increase the size of the object by nine times, increasing the linear dimension by three times, decreasing the resolution by three times (these changes all mean the same thing) and the S/N would increase by three times.

By using Dr. Coltman's results and our knowledge of the number of photons/R at 80 kVp (filtered beam), we can estimate the radiation required for any radiograph or for fluoroscopic imaging for each 0.2 sec (the approximate averaging time for the eye):

$$R/Image = 2 \times 10^{-7} / (RL)(QDE)(d^2)(C - 0.05)^2$$ where

RL is the radiolucency or transmission of x-rays by the object

QDE is the Quantum Detection Efficiency, the ratio of the number of photons which produce flashes or grains to the number of photons incident on the detecting system

d is the diameter in mm of the object of interest

C is the approximate contrast of the object

This approximation is useful for the smallest objects of interest and only when those objects have moderate contrast greater than 5%. Very large objects permit averaging over many pixels and their contrast (measured in terms of the smaller pixels) can be quite small, less than 1%, and the objects still seen very clearly.

We can use this formula to estimate the radiation rate required by fluoroscopic systems. Notice that if the object diameter is decreased and resolution goes up, the radiation needed increases rapidly. Low contrast anatomic objects need more radiation to be seen than high contrast test patterns. An image intensifier of low QDE requires more radiation than a high efficiency tube. And notice that light level isn't mentioned at all!

RESOLUTION

Resolution is defined as the spatial frequency response to sinusoidal objects; a nice definition from a mathematical point of view. Unfortunately, sinusoidal x-ray test objects are hard to make. The usual test objects are lead pinholes, slits or bar patterns and formulas are used to convert the measured data to the

sinusoidal equivalent. The measured data are of the form of "point spread functions", "line spread functions", or the "square wave response". The graph or plot of the sinusoidal result is a measurement similar to that of a high fidelity amplifier expressed in cycles or line pairs/mm instead of cycles/sec (or Hz). Usually, the limiting object size of a system can also be expressed as 1/2 of the reciprocal of the limiting spatial frequency, i.e., if a system responds to 2 lp/mm, then the size of the oject representd by that value is 0.25 mm. The terms, sinusoidal spatial frequency and resolution, are often used interchangeably.

A more precise relationship between the plot of spatial frequency response and object size was developed by Otto Schade for television camera tubes. Dr. Schade solved for the integral of the square of the continuous generating function of the spatial frequency response. He called this term Ne and found it very useful to determine the size of a picture element. In rough terms, the Ne is close to the value of the spatial frequency at around 35%. We really don't care how a system responds to a very high contrast test pattern as much as we want to know if we can see small anatomic objects of moderate contrast. The Ne value is valuable for a very practical reason: the smallest practical object size is just 1/2Ne.

A picture element is usually taken to be of the dimensions of that smallest object of interest. We can consider the entire image plane as made up of a mosaic of picture elements (also pixels or pels). From the paragraphs on noise, we know that the greatest signal to noise ratio, S/N is related to the number of flashes or grains/pixel. The information content of any image is simply this maximum S/N times the number of pixels in the image. We can show that it takes a certain amount of radiation to produce a certain amount of information and nothin' is free!

If we scan this field of pixels in a TV system, the process must have, at least, a number of scanning lines equal to the number of pixels in a column. Actually, for random pixels (as they would occur in real images), the number of scanning lines is made greater than the number of pixels/column by a factor of around 1.4 to be certain that each pixel is scanned at least once. In the process of scanning images, at least 1/2 cycle of bandwidth is needed for each pixel. Thus, the total bandwidth is 1/2 the product of the number of pixels/row, the number of scanning lines/image, the number of images/sec and a loss factor related to the actual method used (around 1.25). Television camera tubes and circuits add noise to the imaging system in rough proportion to their bandwidth and bandwidth is related to resolution. Thus, higher resolution TV imaging systems will require higher dose rates because of fundamental image requirements plus extra noise generated by the TV chain.

DIGITAL IMAGES

Digital computers make possible the storage of images and

processing of images to enhance edges, to average several images over time (more photons/per final image means either less dose or better S/N), to control images and their diagnostic records and to transmit and receive images from other locations. Digitizing images is straightforward as a computer memory location can be used for each pixel and the amplitudes can be expressed in digital values. A image of 512 x 512 pixels can be expressed as an image 9 bits wide and 9 bits high. If the maximum S/N is 256, the amplitude will require 8 bits (one byte). This would be a 256 kbyte image. The eye can discriminate just 6 to 7 bits of amplitude in a single "look" so that an 8 bit image gives enough latitude for slight adjustment. The eye can just resolve 1 degree of arc in a single "look" so that a 512 x 512 pixel image 1 byte deep is adequate for single "look" images.

However, just as radiologists often "hot light" a radiograph to study areas of higher density or search smaller areas for fine details, a complete image may encompass several "look" areas and may require higher than the usual "standard" 512 x 512 pixel images and amplitude range may be greater than 8 bits. In general, when the entire image is seen in a single "look" and the dynamics of that image are under study, the standard image resolution and amplitude are adequate. Stored images, which will be recalled for scrutiny when the x-ray beam is off, can be of higher resolution and amplitude depth (S/N). Stored images require radiation to produce that one image while "real time" images need radiation sufficient to produce a new image every 0.2 sec or so.

SOME SYSTEM CONSIDERATIONS

Every part of the imaging chain and the geometry affect the performance. The focal spot of the x-ray tube is imaged onto the entrance plane of the image intensifier in an interesting way. Imagine that an infinitly small object in the patient acts as a pinhole camera for the focal spot. The image of the focal spot can be projected back into the plane of the patient and would be the smallest size object that the focal spot would permit to be seen. The system geometry as well as the size of the focal spot determine that object size. We want to use the largest focal spot size to obtain the best tube life and lowest cost and the smallest focal spot size to get the best resolution. Obviously, there is an optimum value depending on the application.

The energy distribution of the x-ray beam affects the dose. A "harder" beam produced with constant voltage applied to the x-ray tube and the appropriate filter in the x-ray tube housing will result in the lowest dose. While most fluoroscopic generators are single phase, even when part of a three phase system, the capacity of the cables to the x-ray tube will smooth the voltage to make it almost constant. However, for higher current systems used for therapy simulators or some digital subtraction systems, the cable capacity is not sufficient and three phase or high frequency systems should be used. High frequency systems require far less cable smoothing for near constant voltage operation.

CONCLUSION

We can put these ideas in a series of "does" and "don'ts":

1. System resolution is not free. The resolution should match the application with a lower limit close to the standard value of 512 x 512 x 1 byte/image at standard TV rates. Examine the imaging requirements of that application and design accordingly.

2. Each fluoroscopic image is a radiograph with minimum exposure requirements for each 0.2 sec the eye needs for continuous imaging. Exposure to the patient adds up quickly. All images should show some noise.

3. Minimum radiation requirements are determined by photon statistics. Faster film, more sensitive TV cameras, higher gain image tubes will probably not help much. Once enough light is produced, more light just means that a lens somewhere must be closed a bit to prevent overexposure. The exposure is set for acceptable noise, lenses and sensitivities are set for proper operation (e.g., film density, TV levels, etc.).

4. Image storage reduces exposure because the beam is turned off while the images are scrutinized. Storing a high resolution image results in better images at lower exposure than standard continuous images for obvious reasons.

5. The rest of the system is important. Make certain that the x-ray tube matches the resolution needs. Watch the system geometry.

6. All of the other rules for producing radiographs still apply: minimize field size, use a grid for larger fields and thicker sections, use the proper kVp and filtration. Just because images are easy to produce, don't be fooled into thinking that they're free!

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Fluoroscopic Systems Control, Evaluation and Performance

Joel Gray, Ph.D.

Workshop on Fluoroscopy—
Strategies for Improvements in Performance, Radiation Safety and Control
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Fluoroscopic Systems Control, Evaluation, and Performance

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Abstract

Fluoroscopic systems control, evaluation, and performance begin with the optimization of image quality and dose. This starts with the team approach, i.e., a team effort of the medical physicist, quality control technologist, and in-house service engineers, with the *ultimate responsibility resting with the imaging physician responsible for the facility*. Image quality optimization is dependent upon the appropriate selection of equipment and equipment specifications. Many systems manufactured today do not offer the features needed for optimizing image quality while maintaining patient and staff exposures at reasonable levels. In addition to the appropriate equipment, image quality and dose optimization require aggressive quality control and in-house maintenance programs. These topics as well as typical patient entrance radiation exposure rates (with pulsed-progressive fluoroscopy) and annual staff dose levels will be presented. A summary of patient exposures and fluoroscopic exposure times for over 340 cardiac catheterization procedures, in which only 23 cases required the use of higher than conventional exposure rate levels, will be discussed.

Outline

Fluoroscopic Image Quality and Dose Optimization—Starts with The Team Approach

- The team consists of Medical Physicist (10%), Video Engineer (35%), Quality Control Technologist (15%), In-House Service Engineer (50%) for
  - Six cardiac cath labs, one electrophysiology and one pacemaker lab, and two neuroradiology labs
- Optimized and well-maintained equipment including one lab which is 21 years old and others ranging in age from 2 to 16 years old

Image Quality Optimization Dependent on Equipment Selection and Specification

- Specifications—
  - Image quality comes first, dose follows
  - Performs as well as, or better than, equipment in Room #___
  - Performs to the satisfaction of the staff
  - Numerical specifications for ***systems performance*** including resolution, contrast, brightness fall-off, HVL, etc. (Don't specify what you can't measure!)
  - Specifications for cardiac vs GI fluoroscopy
  - Trade-offs of video, cine, and digital images
- Plumbicon camera tubes, minimum lag with maximum resolution
- All video monitors calibrated using standard (1.0 volt peak-to-peak) test pattern
- Video signal optimized by use of remote control iris, i.e., signal recorded on video tape is optimized
- Elimination of grids whenever possible—dose reduction of 2X
  - During fluoroscopy for all conventional fluoroscopy, interventional procedures in neuroradiology, electrophysiology procedures and pacemakers, pediatric cardiac procedures (not for cine filming)
- Pulsed-Progressive Fluoroscopy (PPF)—dose reduction of 2X
  - Only radiation protection measure which resulted in reduction of personal monitor exposures
  - Radiation doses decreased while number of studies per cardiologist increased and the total number of PTCAs increased
  - For all cardiac fluoroscopy (usually requires grid pulsed x-ray tube)
    - Would like to install this for all interventional fluoroscopy and, ultimately, all fluoroscopy but manufacturers are hesitant since the "customer isn't asking for it"

The Ideal Fluoroscopic System—or What the Manufacturer Should Supply!

Increase minimum HVL (to at least 3.0 mm Al vs 2.3 mm at 80 kVp)
Pulsed-progressive fluoroscopy should be required for interventional and special procedures
Grid automatically removed for fluoroscopy, automatically inserted for radiographic or cine imaging
Eliminate 5 R/min maximum exposure rate when high level control (HLC) is present
Eliminate high level control
Manual remote control and automatic iris—prevents light starved video (eliminate need for HLC?)
Automatic digital window and level for fluoroscopy, and digital display
Limit fluoroscopy to 70 kVp and above
Eliminate access to brightness and contrast controls on video displays
Require cumulative fluoroscopic time display on video monitors
Variable apertures in imaging chain
C-arms for electrophysiological procedures must have a non-removable spacer to maintain minimum source-to-skin distance
Automatic focal spot selection (small all of the time except on demand for steep angle projections, i.e., high heat loading)

Image Quality and Dose Optimization Require Quality Control and Good Maintenance Procedures

Quality Control
- Major equipment evaluations every three months, including image quality and patient exposure rate measurements
- Processor QC daily before any film is processed
- Resolution, density, and contrast phantom on every cine film and video recording as part of patient identification
- Cine projector and video display QC monthly

Maintenance
- All maintenance by in-house x-ray service engineers, i.e., no contracts
  - Results in significant cost savings and minimum down time
- Preventive maintenance every month, rotating schedule of activities

Typical Radiation Exposure Rates (Pulsed-Progressive Fluoroscopy with Grids)

Fluoroscopy	6-inch—	1.5 to 2.0 R/min
	9-inch—	0.70 to 1.00 R/min
Cine	6-inch—	15.0 R/min
Video Record	6-inch—	2.0 to 2.5 R/min (Low), 4.0 to 4.5 (High)

Typical Staff Radiation Annual Dose Levels (1991)

Number of diagnostic cases per year— 4,407
Number of PTCAs per year— 1,140
Number of cardiologists— 15
Number of residents— 7

Annual Staff Doses
- Average— 0.79 rem/year
- Maximum— 3.45 rem/year

Typical Resident Doses
- Average— 0.51 rem/month
- Maximum— 0.80 rem/month

Management of high personal radiation monitor readings and long fluoroscopic times

Dosimetry '91 Study Summary

342 cardiac procedures
- Of these 64 were interventional procedures (PTCAs or PTCAs with laser)

Only 23 used increased exposure rates
- Only used to provide better visualization of inflated balloon for dilatation procedures
- What proportion exceeded 10 R/min?
  - Is HLC needed in an optimized facility?
  - Some facilities always use HLC due to 5 R/min limit
  - What role does video recording play (circumvent regulations)?
- Average fluoroscopy times for various procedures [Average (standard deviation, range)]—

Coronary angiography (CA)	7.5	(7.0, 1.0 - 43.0) minutes
Left Ventriculography plus CA	9.7	(5.4, 2.0 - 39.0)
PTCA	31.1	(26.6, 5.0 - 121.0)
Laser-PTCA	43.8	(25.1, 24.0 - 95.0)
Electrophysiology—Diagnostic	9.7	(5.7, 0.5 - 20.0)
Electrophysiology—Therapeutic	87.6	(64.2, 41.0 - 179.0) (n=4)

Evaluation of Systems with High Level Control Mode

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High Level Control Fluoroscopy for Image Enhancement

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Introduction

High level fluoroscopic boost options that exceed conventional fluoroscopy exposure limits are available as a means of reducing quantum mottle during fluoroscopy. Federal law currently does not specify exposure limits but does require specific means of activation to safeguard against inadvertent use. High Level Control (HLC, a term which is taken directly from the Federal Code of Regulations Title 21), is marketed under several different trade names and is available from various manufacturers as a standard item or as an option on fluoroscopy equipment. Although HLC increases the exposure rates to the patient and the staff, its use is supported, in part, by improvements in image quality. However, based on a limited survey of HLC equipped machines, there is a large disparity between recommended and actual HLC exposure limits as well as no industry coherence in HLC designation or means of activation. With the proliferation of "non-invasive" interventional procedures that often require several *hours* of fluoroscopy time, HLC's ability to improve image diagnostic quality can reduce total fluoroscopy time, offsetting the exposure rate increase.

Patient entrance skin exposure under normal fluoroscopy is limited to 10 R/min by the FDA. Fluoroscopy machines that are equipped with High Level Control may exceed the normal limit as long as "continuous manual activation is provided by the operator and that there is a continuous audible signal." The manufacturers have coined several different terms to refer to HLC fluoroscopy. These include fluoro boost, high contrast, image enhance, low noise, and image record modes, to name just a few. One potential difficulty in the variety of terminology is that the fluoroscopist may be unaware that they have invoked a high exposure mode. Many of these same terms are also used to describe other functions, specifically digital image post processing that of course has no increase in exposure. It is our experience that the some fluoroscopists may be unaware of the difference.

The FDA does not mandate an HLC exposure limit, however, other (non-regulatory bodies) have made recommendations as to what the maximum exposure limits should be under High Level Control (figure 1). The AAPM[1] states that "it is considered good practice to limit high level control to 10 R/min (2.6 mC/kg-min) unless a specific clinical need has been identified." The County of Los Angeles[2] recommends that the maximum exposure rate not exceed 15 Roentgen per minute and the FDA[3] has proposed to limit HLC fluoroscopy to 23 R/min (20 cGy/min). All of these limits seem on the onset to be somewhat arbitrarily set and may not be in accordance with what may be required in a given clinical setting. The following

report is a presentation of the maximum exposure rates measured from surveys of machines at various institutions for fluoroscopy with HLC and normal mode. Also, some preliminary image quality comparisons are shown here that demonstrate HLC has an advantage over conventional fluoroscopy with large patient thicknesses.

Investigation of maximum exposure rates for HLC

Our survey included data from six different institutions with eight different machines tested from four of the major manufacturers, including Philips, Toshiba, Siemens, and OEC\Diasonics. To ensure data consistency, the method for measuring the maximum dose rate was rigorously outlined. The measurement geometry shown in Figure 2 is described in the Federal regulations 21 CFR 1020.32 d.3. The ion chamber is placed 30 cm. from the image intensifier. The automatic exposure control is driven to maximum technique by blocking the face of the image intensifier with lead. The surprisingly high levels of dose delivery for the various machines are reported in Figure 3. Of all the units tested, the maximum reported exposure outputs in HLC fluoroscopy varied from a low of 21 R\min to a high of 93 R\min. The mean of the exposure rates for the eight machines tested was 52.6 R\min, more than 5 times the AAPM recommended limit. It is important to note that machines from the same manufacturer had exposure rates that varied by 42% and that two machines of the same model from another manufacturer varied by 16%.

Investigation of exposure rates for typical patient with HLC

The exposure rates presented reflect maximum machine output and would only occur with a very large patient and/or an extreme projection angle. In order to compare exposure rates for a typical patient size with conventional and HLC fluoroscopy, the measurement geometry in figure 2 was used substituting a standard 7&7/8" lucite phantom for the lead.

Figure 4 shows that the exposure for a typical patient increased from 2.3 to 6.6 times merely by activating HLC. Of the machines tested the highest exposure rate for a normal sized patient in a simulated PA projection with HLC engaged was 21.3 R\min, more than four times the exposure rate that the State of California mandates as the limit for an average size patient in the mode of least magnification. In all cases, the exposure rate was immediately increased by at least a multiple of two or more as opposed to a gradual increase in output that the operator can control.

Methods of HLC Activation

The degree of difficulty of engaging HLC also varied widely from machine to machine. The FDA requirement for continuous manual activation has been interpreted in many ways as

summarized in Table 1. In the simplest case, where normal fluoro is made by stepping halfway down on a two position foot switch, HLC fluoro can be activated by pressing the foot switch all the way down. The most extreme example of initiation of HLC required two people; while the physician in the room depresses the foot switch, another individual in the control booth must turn a key and simultaneously push and hold a button. If any of the three switches is opened, HLC mode is interrupted. In both cases compliance with regulation is met as there is continuous manual activation.

Image Quality Assessment of HLC

A preliminary image quality comparison was conducted to compare images generated from normal automatic brightness control fluoroscopy and HLC for different thicknesses of lucite. The studies include a high contrast evaluation with a line pair phantom, and low contrast evaluations with vessel phantoms and a lucite step wedge. Relative radiation exposure rates for each phantom comparison were also measured. An OEC-Diasonics Series 9000 mobile C-arm was used to create both the normal mode and HLC images for increasing lucite thicknesses. For each image pair the device automatically selected the kVp and mA. When HLC was engaged the mA was boosted while the kVp remained constant.

HLC fluoroscopy showed no significant improvement of visualization of high or low contrast line pair resolution for lucite thicknesses less than 5-inches (12.5-cm), despite a 3-fold increase in exposure. At thicknesses greater than 5-inches the authors were able to distinguish one to two high contrast line pair increments more with HLC than with normal mode (Figure 5). The improvement in resolution required an increase of exposure rate ranging from 600% at 6 inches lucite to 850% at 15 inches. With the low contrast vessel phantom (Figure 6) and line pair phantom the authors were able to visualize up to three more vessels and line pairs with HLC at lucite thicknesses greater than 5-inches. The increase in low contrast performance also required a nine-fold exposure rate increase. The low contrast step wedge demonstrated that the ability to distinguish steps as a function of the signal-to-noise ratio was improved with HLC. While signal-to-noise decreased in both modes with increasing lucite thickness the improvement in detecting steps was superior with HLC by approximately 50% (Figure 7).

Conclusions and Discussion

Based on this survey, it would appear that not only is there no coherence with recommended exposure limits, but that there is also no industry standard, even for a given model machine. In all cases the equipment operated legally, but the exposure levels achieved are surprising. Follow-up inquiries made to manufacturers suggest that some machines may have been modified to achieve the high exposure levels found in this study. The survey also

demonstrated a lack of congruency in the method of activation of the HLC. The intent of the regulation is clearly to make the operator cognizant that the HLC is engaged, yet the methods of activation ranged from trivial to a concerted effort by two operators.

The questions raised by this study are:

(1) Should there be governmental regulations regarding the limits of HLC exposure? The recommendations seem to have arbitrarily set limits for HLC (i.e. 10, 15, or 20 R/min), much lower than the values seen in the study.

(2) Should exposure limits be set by the physician, the physicist, by the manufacturer, or all three? Currently the exposure levels are typically set by the manufacturer or, in practice, by the installation or service engineer.

(3) Do the methods of engaging HLC fluoroscopy satisfy the intent of the law? The study shows that there is a large disparity in the manufacturer's interpretation of the regulations. It would seem to be a more important consideration that the operator be aware of the exposure magnitude, and not confuse HLC activation with post image processing.

(4) Should machines with HLC capability be restricted to 5 R/min maximum in the normal mode? This may force the physician to use the HLC mode more frequently since a 5 R/min (versus a 10 R/min) limit may present an unacceptably noisy image. Limiting the normal mode may actually result in more patient dose being delivered since HLC would be activated more frequently.

(5) Should there be an obligation on the part of the vendor to clearly document the actual maximum exposure rate for the HLC machine? Due to the high exposure rates involved it is crucial that rate be monitored and the physician informed. Perhaps physicians could better serve the patient by having a real time display of integrated patient exposure.

(6) What sort of filtration is being used in the fluoroscopy tube? Small differences in the amount of filtration could dramatically change the exposure magnitude. If it is only appropriate to use HLC when there is a great patient thickness, then increased beam filtration would be appropriate.

1 American Association of Physicists in Medicine. *Protocols for the Radiation Safety Surveys of Diagnostic Radiological Equipment*. Report No 25. 1988: 31-32

2 <personal communication> Kaufman K, County of Los Angeles, Department of Health Services.

3 Center for Devices and Radiologic Health. *Radiologic Health Bulletin.* Volume XXIV, No12 December 1990